A review of Certificate of Need health care policy programs:

At the intersection of science and politics

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Research about CON

- many conclusions state more than the research underlying them is competent to conclude.
- researchers of CON have often offered conclusions even if the data and research methodology were inadequate for the purpose.

This CON Review

- historical and quantitative approach,
- interviews
- three CON case studies, in Alabama, Oklahoma, and Illinois.

There ARE Findings:

1. Neither CON nor competition models appear to have had much impact on the extreme increases in health care costs that have plagued the American economy since at least the 1960s.

- 2. There is evidence that CON has had <u>some</u> positive effects on hospital capital expenditures, mostly by encouraging more planning, by having a sentinel effect on growth, and by slowing down some expansion plans and duplication of services.

- 3. The traditional “market failure” and “public good” characteristics of health care that served as the rationale for regulation still exist:
  - a. the social goal (and legal requirement) of care being provided regardless of ability to pay
  - b. demand largely being determined by the same party that supplies the services
  - c. guaranteed payment for almost all the services providers can provide.
  - d. lack of effective competition in many markets, either through natural factors such as geography, regulatory factors such as CON, or predatory market practices such as anti-competitive mergers and other cartel behaviors

- e. hospitals not competing based on price, but rather competing for the allegiance of doctors by increasing facilities, adding equipment, paying larger salaries, and instituting prestigious programs such as heart surgery
- f. there is evidence that when hospitals lose business to competition, either other hospitals or ambulatory surgery or diagnostic centers, they do not lower prices. Rather, they raise prices on the other services the hospitals still provide and for which they still have a monopoly in the market
- g. consumers have little ability to influence whether they need hospital services and generally do not comparison shop for hospital services when they do need hospital services

- h. most people have third-party reimbursement (either private insurance or government benefits) for their hospital expenses and are generally unaware of, and not responsible for, most of the cost of treatment
- i. one aspect of the system, the Medicare and Medicaid programs, can mitigate utilization and charges, but is only partially successful because providers are able to cost-shift (charge more than cost plus reasonable profit) to other payers, especially insurance companies
- j. the primary impact of market failure and public good features is a health care system that can basically be as big as it wants to be and be guaranteed that someone (either government programs or third-party insurance) will pay whatever charges it sets

- 4. The health care system is dominated by a paradigm that thwarts most attempts at cost control: this paradigm is the guaranteed, third-party payment to providers who influence demand and determine charges, and who have few incentives for price or cost competition.
- 5. One of the dominant conflicts in modern healthcare, particularly concerning hospitals, is between established hospitals trying to maintain monopoly power and entities such as ambulatory surgery centers that are trying to enter the market.

- 6. Two ideological schools, one labeled “pro-regulation” and one labeled “pro-competition” are locked in conflict over the future of health care, and virtually all health care policy issues, concepts, and proposals tend to be pre-judged based on which of these ideological camps the policy makers, researchers, professionals, or consumers identify with.
- 7. Neither an increased and more effective regulatory system nor a well-functioning competitive system are likely to occur in the foreseeable future. The former would require substantial control over providers and the latter would require destruction of current programs of guaranteed third-party payment, consumer protection, guaranteed issue, and equity mandates.

- 8. Realistically, the alternatives are:
- A. accept the current paradigm: that health care will continue to consume larger and larger shares of the gross domestic product and of state and federal budgets (already 20-25% of state budgets);
- B. make incremental progress, "bend the curve": making modest adjustments to regulations, encouraging more consumer involvement in health care decision-making about services and benefits, encouraging providers to be more efficient, encouraging healthy lifestyles and disease management programs, trying to change reimbursement mechanisms to pay providers more for prevention efforts and less for acute care, working to support continued financial health of insurance plans;

- c. experiment in several states with new funding and delivery models such as single-payer, mandated-insurance, reduced regulation, or new methods of introducing competition;
- d. replace the blank check health care financing system with a defined bank balance: find a mechanism to either set providers' rates or create annual budgets for providers and give them the freedom and responsibility to manage within those budgets.

Some History

- Adding to the impact of guaranteed third party payment of usual and customary charges was the so-called "Roemer Effect" – the principle that a bed built is a bed filled.
- Requiring Certificate of Need (CON) before undertaking capital expenditures was seen as the "most effective way to control utilization and third party expense [by controlling or reducing] supply."

- Significant assumptions about the health care marketplace underlay the enactment of CON laws:
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- - Capital costs in health care are passed on to consumers
- - Competition in health care does not lead to decreased charges because providers control supply and also determine much of the demand, and because consumers lack information
- - Consumers don't shop around for health care, at least not based on price
- - Increased costs lead to increased charges
- - Consumers don't pay most of the cost and don't really know the true cost of, and charges for, care.

- Providers have no direct incentives to lower charges or utilization

Measuring CON's Effectiveness

- could look at the number of CON applications denied
- what if, especially some years after the CON program has been in place, some applications for capital expenditure are not submitted because the providers expect they will be denied?

- as providers learn what is likely to be approved and what is not, and as CON guidelines and policies are developed, indicating what the capital spending priorities are in a state, one would expect applications that suit the guidelines to dominate the total number of applications submitted.

- the “sentinel effect” of CON - stopping capital projects before they become CON applications.
- measuring the success or failure of CON should not just look to the dollar amount of proposed projects approved and denied, but also to the long-term operating costs that flow out of capital projects undertaken. Typically, researchers assessing the savings achieved by CON have only added up the capital construction dollars or medical equipment dollars identified in the application.

- Likewise, CON opponents sometimes complain that proponents' claims of health care dollars saved through CON ignore the costs involved in participating in and complying with the CON process.

Implementation Problems

- 1) difficulties filling statutory gaps: how to treat leases, personnel costs, grants, donations, transfers, mergers, etc. when determining jurisdiction over health care facility capital expenditures, the splitting up of projects, and the phasing in of projects over two or more years in order to avoid jurisdictional triggers,
- 2) providing enough due process but not so much that delay cost more money than would be saved by good policy decisions,

Implementation Problems

- 3) determining who would make CON decisions (appointed boards, state agencies, governors, etc.), and
- 4) problems defining the criteria to be applied, in particular the problem of determining the definition of "need" for health care projects.

- Perhaps the overarching difficulty with CON programs arose from the stated goals:

  "Most CON programs, including the federal one, have one stated goal: ***the promotion of equal access to quality health care at reasonable cost.*** The problem is that this single, seemingly unimpeachable goal is in reality three goals that compete and are often mutually irreconcilable: quality, accessibility, and cost control." (emphasis added)

How to Define Need?

- prove a system failure will result without the proposed expenditure being undertaken? see need as being about quality: need to undertake the expenditure in order to maintain or improve quality.
- see accessibility as the major goal
- see CON as having one essential purpose: to keep costs down.

How to Define Need?

- Indeed, when CON was initiated some regulators thought its purpose was to set the stage for a pending national health care solution that would solve the cost problem systemically. The primary problem to be addressed by the federal CON legislation was rapidly increasing health care costs, not lack of quality or serious access problems.

Oklahoma Case Study

- Called to construct the City of Faith – a $250 million medical complex including research and diagnostic buildings and a 777 bed hospital, all adjacent to Oral Roberts University in Tulsa, Oklahoma. Tulsa County, however, had ten underused and financially pressed hospitals that reported a total of 1,000 empty beds daily. The Oklahoma Health Systems Agency turned down Roberts' request to certify yet another hospital.

Oklahoma Case Study

- Roberts used his world-wide mailing list, and half a million letters of support swamped the state capital. Roberts' lawyers argued that it was these followers, rather than citizens of Tulsa, who would fill up the hospital. Both houses of the Oklahoma legislature passed resolutions urging the commission to approve the application. The commission voted unanimously to allow Roberts to go ahead with a 294 bed hospital and add the rest of the 777 beds later.

- The hospital rose 60 stories tall above Tulsa and was completed in 1981. Oral Roberts said it cost $250 million but was opened debt free. In 1989, with most beds never filled, Roberts closed the hospital saying that God told him to close it. The Medical School also closed. The Medical Research Center, planned to be 21 stories tall, only had 3 stories developed by 1984. The hospital operated in the red for all but two months of its existence

- CON Proponents could argue that had the CON process been characterized by more science (judge the need for the hospital on the facts) and less politics (giving in to pressure from the legislature, hundreds of thousands of letters and thousands of phone calls), the hospital would not have been built and many resources would not have been unwisely spent.
- Opponents could argue that a scientific CON process devoid of excessive political influences has never been developed and this case illustrates that vividly. Perhaps, they would argue, it would have been better to avoid spending time and money trying to evaluate such projects and just let them succeed or fail of their own doing.

More Solutions than We Use?

- advice from 1978 about how to improve CON process:
- - compare methods for meeting a perceived need
- - ensure that lower cost alternatives are identified in order for comparisons to be made

More Solutions than We Use?

- - have competitive reviews through a batching process. As an example, the Federal Communications Commission holds competitive proceedings to allocate a limited number of broadcast station licenses
- - engage in more planning in order to do it well and so as not to just be reactive
- - develop and maintain an independent viewpoint skeptical of providers' claims of need

More Solutions than We Use?

- - ensure good staff work emphasizing the importance of cost controls and the need to demonstrate positive results for the population served

More Solutions than We Use?

- - ensure the staff can provide a contrary point of view to the applicant: “Applicants can be relied upon to underline the strengths, as they see them, of their proposals; as a counter, staff should focus on weaknesses and should develop an independent point of view. In fact, resources, permitting a designated staff member should probably oppose all applications; a devil’s advocate role is useful even when decisions may seem obvious.” Such advocacy should highlight issues and help reviewers work toward independent standards on a case-by-case basis.”
- - have non-applicant presentations such as are provided through the Massachusetts “ten-taxpayer” groups (any group of ten taxpayers may demand party status to intervene in an application)

More Solutions than We Use?

- - have secret balloting by the decision making body to prevent providers from profiling commission members and lobbying them over time
- - reviewers should be skeptical. Make applicants prove improved health of the population served – a "show me" attitude. Reviewers should "strive to make applicants show need in social terms – results for patients and populations – rather than in terms of medical process or institutional needs."

More Solutions than We Use?

- - make comparisons between providers as a proxy for quantitative standards
- - don’t use an approach that assumes a CON should be granted unless the staff can prove otherwise. The burden of proof needs to be on the applicant

More on "Does CON Work?"

- four decades since Milton Roemer's observation about the utilization-increasing effects of excess health care facility capacity, the so-called Roemer Effect.

More on "Does CON Work?"

- Factors such as the expanding prevalence of third-party payment for the cost of treatment seem to be giving the Roemer Effect a long life.
- "Several studies provide empirical evidence of extensive duplication of services and redundant hospital capacity in competitive markets. When cost-reimbursement policies provide easy financing of the associated cost, competition drives capacity up, because hospitals develop a full range of services to attract and retain medical staff and patients."

More on "Does CON Work?"

- In June of 2000, the Finger Lakes Health Systems Agency, based in Rochester, New York, published a study entitled "Capacity Matters." In its report, the agency provides a strong argument that Roemer's Effect is alive and well, at least in the Rochester area. The group concluded that there is substantial evidence that excess capacity leads to increased costs, under-utilized facilities and increased use of health care services. The study also found that excess capacity and utilization may also:
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- - jeopardize quality of care
- - lead to heightened competition and loss of cooperation among providers
- - result in a loss of medical management to non-physician reviewers
- - lead to loss of community control
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- As evidence of excess capacity in the Rochester area, the study noted declining rates of hospital occupancy, the substitution of ambulatory services and the conversion of hospital beds to other uses. Despite decreasing occupancy, however, "hospitals continued during the 1990s to renovate and in some instances build new facilities largely of the same size."
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- hospitals might, however, correctly claim they were responding to the lower occupancy rates by reducing the size of the units and providing what their consumers wanted by modernizing the units.
- hospitals should also be able validly argue that all capital facilities must be replaced over time.

- The report cited the following effects of excess capacity:
- - establishment of a new ambulatory care facility at the same time there is considerable vacancy at the hospital means the hospital will increase prices even if it can reduce staff and close operating rooms because it has to pay fixed costs.
- - expansion of service in states that repealed CON: In Phoenix, Arizona, five new cardiac catheterization programs, which had previously been rejected by the CON program based on lack of community need, initiated within the first year after repeal of CON controls; volume at each program was well below optimum…

- “Bryce and Cline demonstrated that in the six years following repeal of CON in Pennsylvania, lithotriptor supply doubled, procedure volume per machine fell from 773 to 489, against a capacity of 1,000 to 2,000 per machine. Average operating cost per procedure in 1994 was estimated to be $2,107, but would have been only $1,331 if each machine were performing 1,000 procedures.” Also, Pennsylvania’s MRI capacity more than doubled and volume per machine dropped to between 60 and 75 % of state guidelines. Cardiac catheterization lab capacity increased 90% and the average volume fell from 1,034 to 758 per lab. By contrast, in the Rochester area at that time average volume was 1,750 per machine.
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- indicated that where excess capacity exists, evidence suggests physicians use more medical procedures. Similar patterns have been shown with the supply of doctors and of high-tech equipment
- also reviewed the modern concern that excess capacity can negatively affect the quality of care: “If a specialist does too few cases, quality deteriorates”

- Bryce and Cline reported, for instance, that 15% of Pennsylvania catheterization labs do not meet minimum volume standards. The American College of Obstetrics and Gynecology, the March of Dimes Foundation, and the Federal government have concluded that quality of care improves with increasing obstetrical unit size and with a minimum standard of 50 births per year.

- An October, 2002 report in the Journal of the American Medical Association indicated that risk adjusted mortality was 22% higher in the 18 states that had no CON regulation for open heart surgery than in the 26 states (and D.C.) that had continuous CON regulations. The higher mortality was observed in all six years of the study
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- The Rochester study also claimed excess capacity fosters unproductive competition for doctors and business in services such as obstetrics.
- At the same time, the study claimed there is substantial under-investment in prevention services, information technologies, and addressing shortages of nurses and other health personnel.
- The authors indicate that the elasticity of increased use is found to hover around 53%, i.e., a 10% increase in the number of beds will produce a 5.3% increase in bed days

HealthSouth Case Study

- In 2002, HealthSouth wanted to build a state of the art, $240 million “digital” hospital. It would replace a 169 bed hospital HealthSouth owned in Birmingham. But Alabama had a fairly rigorous CON law and other hospitals in and around Birmingham opposed the project. Rather than go through the CON process, HealthSouth convinced the Alabama legislature to completely exempt the project from CON law. CON has existed in Alabama for 17 years and this was the first exemption by legislation.
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- Not-for-profit Baptist Health Systems and Brookwood Health Services (owned by Tenet Healthcare) sued to block the project, although it was already under construction. They claimed the exemption law was not public noticed as required by law prior to enactment. HealthSouth threatened that without a CON waiver it would build the hospital in another state rather than put up with the CON process in Alabama that HealthSouth claimed would delay the project for six years. A trial, expected to take two years to start, would be too late to stop the project. By that time the hospital would already be built and operating

- The plaintiffs in the suit also claimed HealthSouth misled Alabama lawmakers in order to obtain tax breaks and the regulatory exemption, including an estimated $30 million tax break over 10 years from the city of Birmingham. HealthSouth's claims that this would be a unique "digital" hospital were also challenged, with opponents claiming it would really not be any different from computerization other hospitals had.

Behavioral Hypotheses of Regulation

- **Producer-Protection Hypothesis**
- **Prisoner of the Hospital Industry**
- **Tool of an Industry Cartel**
- **Friend of Industry Insiders**
- **Facilitator of Industry's Good Works**
- **The Taxation-by-Regulation Hypothesis**

Behavioral Hypotheses of Regulation

- **The Brushfire-Wars Hypothesis:**
- agencies get caught up in fighting brushfires rather than accomplishing meaningful planning.[i] Havighurst described this "fighting brushfires" type of regulation as follows:
- "Absorbed in deciding inconsequential issues of equity such as which of several applications shall provide a given service, the agencies are unable to perform the socially more important job of prescribing the industry's structure, determining which services should be offered, and deciding how needed change can be promoted. "

Behavioral Hypotheses of Regulation

- The reason most frequently offered for lack of planning, according to Havighurst, is lack of agency resources. Also, the issues to be dealt with in planning are often difficult, controversial and intractable:
- - "…types, sizes, age, condition, and distribution of facilities; use patterns, including service areas within hospitals; population characteristics and size; availability and accessibility of services and facilities; supply of physicians and other health personnel; income levels; levels of medical technology in the community; health insurance coverage; climate; and the habits of people."

Behavioral Hypotheses of Regulation

- - the need to include projecting changes in population, technology, health care financing, delivery systems, and patterns of utilization.
- - the degree to which agencies lack faith in their ability to make hard-and- fast judgments, lack firm standards, and succumb to the pressures of politics necessarily becoming dominant.

Other CON Reform Ideas

- Havighurst recommended the following modifications (decades ago), many of which are now being debated as reform ideas:
- - limit provider influence in the process.
- - CON decisions should be made by an agency "which bears direct political responsibility for the cost of health care as a purchaser of care under Medicaid and state employee health programs." Note Tennessee CON reforms
- - limit CON to hospitals and exempt HMOs

Other CON Reform Ideas

- - have a very open process and require detailed findings of fact and full statements of reasons and dissenting views as to particular decisions
- - mandate reliance on real planning
- - if departing from published plans, do so to reflect express commitments to increasing consumer choice, strengthening competition, reducing costs, and encouraging innovation.

Other CON Reform Ideas

- - the need requirement should not shelter non-cost related pricing or prevent entry by providers providing less comprehensive care except where care of indigents would unavoidably be jeopardized.
- - the law should be sunsetted so as to serve as a moratorium, not permanent regulation.
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Qualitative Data

- State A: CON penetration is moderate; CON provides a sentinel effect on new projects; the business community is behind it; health insurance premium increases are high (25-41%); the history has been a patchwork of fits and starts, legislative updates, provider-driven changes to CON; a need for more scientific criteria; need for a new state health plan; Medicaid cost crisis is severe; fifth oldest population in the country; politically divided legislature; lots of conflict between the needs of the inner city hospitals and the rural ones; serious tort reform issues on the table; unions and business coalitions are strong and they support CON.

Qualitative Data

- State B: believes its system is different than other CON states because they have "taken the politics out" of CON and focus on whether the applicant has the qualifications to run a high quality health care service; banned ex parte communications; the CON application process is a "legal process" rather than a "counseling session"; criminal penalties for each violation lasting for 7 days, fines also; believes big business is spurring renewed interest in CON; there is one decision-maker although councils make recommendations; the agency is run in a very "no-nonsense" way but very "customer service focused"; totally focused on how good the data provided by the applicant is and "making sure that persons/organizations who provide health care are competent to do so."

Qualitative Data

- ¨ State C: extensive jurisdiction that applies to parent companies of health care facilities as well; deals with termination of programs also, not just new programs; the criteria have been made shorter and simpler; assessments are tied to budgets; has police-like investigative powers; tied to hospital rate approvals which the state also handles; has waivers for equipment replacement; has a law against shifting costs to uninsured persons.

Qualitative Data

- ¨ State D: heavily involved in surveying facilities and developing mathematical criteria for need; broad public participation in state health plan development; extensive jurisdiction over facilities and types of services; substantial fines for violations ($5,000 per day); requires charity care commitments; favors regionalization of services; invites alternative health care models; imaging equipment must meet utilization targets to get approved; extensive definitions of services.

Qualitative Data

- State E: CON has primarily kept access available in a rural environment; has had a sentinel effect delaying projects and discouraging every hospital from having everything; the program needs new blood; given small staff, covering too many things jurisdictionally.

Qualitative Data

- State F: CON law lapsed and new services rushed in; government dealt with it by focusing on public health issues and disease management, looking at the root causes of utilization such as smoking, diet and lack of exercise; increased quality monitoring; some hospitals would like CON to return but the legislature doesn't seem interested; cost increases are now blamed on nursing shortage and malpractice insurance crisis; tobacco settlement money is being used as a stop gap to help hospitals in need get equipment (65% of tobacco money spent on high tech imaging equipment which some now say is oversupplied).

Qualitative Data

- State G: light penetration, decreasing steadily since the mid 1990s, constant attempts in legislature to end CON except for long-term care; very interested in research comparing CON and non-CON states, feels there is a real lack in this area; open-heart is the big topic now; hospitals, nursing homes and hospices want very much to keep CON; substantive debate lacking, just regulation vs. market talk; drug costs and Medicaid costs are center stage politically; term limits have seriously depleted institutional knowledge of CON at the legislature; many legislators are gung ho for competition but change their minds when they focus on preserving their local hospitals; fear of boutique hospitals.

Qualitative Data

- State H: biggest battles in recent years have been between hospitals and ambulatory surgery center proponents – this has given CON a big profile in the public; CON has a prophylactic effect; new groups of legislators get interested in getting rid of CON but then get scared by health care costs, especially Medicaid, and leave it alone; has only one community with competition between hospitals; gets a very high Medicare reimbursement rate; aging population; high alcohol and drug use, accidents, trauma; health care ranks below education, budget balancing and other issues.

Qualitative Data

- State I: lots of task forces and such debating what to do with CON; it makes the hospitals plan better and propose what will be worthwhile; staff gets asked by legislators to show proof it works and can't; focuses on quality of care and access (regionalized access) a lot; hospitals want to keep it; one large tertiary care hospital skews all the numbers.

Qualitative Data

- These themes emerged from the interviews:
  - CON is not breaking new ground but is fairly entrenched in most states surveyed
  - Hospitals are among the strongest supporters of CON Legislators and other stakeholders are conflicted by multiple goals
  - Most states are engaged at some level in debates about what to do about health care costs but there is a lack of ideas that can command consensus or break through the regulation-competition ideological divide
  - Research is lacking and support of or opposition to CON is based largely on anecdotal and emotional information

Regulation, Deregulation, Regulation, Deregulation, …

- Texas, Tennessee, California and Virginia removed CON application to home health agency development in recent years. Tennessee reinstated it, however, after rapid growth in HHAs "threatened to destabilize the entire industry".

Regulation, Deregulation, Regulation, Deregulation, …

- Other states have imposed moratoria on issuance of new HHA CONs: Florida, Georgia, Alabama, Kentucky, and Mississippi. (prevalence of capitation as a payment source in home health).

Regulation, Deregulation, Regulation, Deregulation, …

- In 2001 CON critics in New Hampshire launched an effort to do away with CON, saying the CON board "favors the state's 28 hospitals over doctors, medical practices and other health care providers, preventing true competition in the state's health care system." The board's defenders pointed to research indicating that health care is better because of regulation and that "'while there is market concentration (of hospitals) there is not market abuse'" Study also found the allocation of health care resources well-distributed.

Regulation, Deregulation, Regulation, Deregulation, …

- Elizabeth Crory, Chairwoman of the CON board, advocated looking at eliminating the thresholds because of a lot of "gamesmanship" from health care developers who try to avoid a CON by "using creative ways of keeping the proposal under the threshold.". "Some of the applicants have got quite clever in coming up with means of getting around the law," the former Hanover state representative said, "such as leasing the equipment in order to lower the cost."

Regulation, Deregulation, Regulation, Deregulation, …

- In 2002, in Maine those favoring repeal argued that new health care services are great, and competition creates better prices, higher quality and options for patients. Those favoring keeping CON replied that supply will outweigh demand, providers will shift losses to other areas, and costs will go up for everybody with higher insurance premiums and reduced benefits resulting.

Regulation, Deregulation, Regulation, Deregulation, …

- The Maine Medical Association, representing doctors, favored repeal of CON, contending that managed care will control health care spending. The Maine Hospital Association disagreed, fearing that repeal would hurt hospitals via cream skimming. The Medical Association's expert contended research proves that the 14 states that abolished CON are not seeing higher healthcare costs than states that still have CON. Supporters of CON touted research showing better quality outcomes in places with higher volumes.

Regulation, Deregulation, Regulation, Deregulation, …

- In Tennessee, a major change in the program involved how CON considered projects' potential effects on TennCare, Tennessee's health care insurance program for low-income people. The reform legislation mandated that the effects on TennCare be taken into consideration with every CON application.

Regulation, Deregulation, Regulation, Deregulation, …

- According to Rosie Pryor, Director, Marketing and Planning, McKenzie-Williamette Hospital, Springfield, Oregon, "…there is a backlash forming after 20 years of mergers, acquisitions and CON laws that failed to control rising costs." She claims that "…all that did was eliminate competition for some and help create the mega-hospital systems now throwing their weight around in their respective markets." Now, according to Pryor, these larger, more-expensive hospitals are pushing back against insurers "that seek to highlight comparative hospital costs through tiered network plans or simply by ranking facilities according to cost in plan member handbooks…"

Regulation, Deregulation, Regulation, Deregulation, …

- In Georgia in recent years, the CON battles included two hospitals competing over the provision of cardiac care services, two other hospitals fighting over which would get to build the first hospital in a particular suburb of Atlanta, and still two other hospitals teaming up to oppose a third hospital's bid to open the first new cardiac unit in metropolitan Atlanta in almost 20 years. One of the most often heard arguments in Georgia in favor of the regulation is that it gives public hospitals an edge over those that don't treat as many indigents.

More "Does CON Work?"

- James Blumstein and Frank Sloan (1978) noted the significant problems inherent in trying to evaluate the effectiveness of CON:
- - lags between project conception and when the doors open
- - significant amounts of "grandfathering"
- - states facing unusually high rates of hospital cost inflation might be among the first to adopt CON.
- - interactions between CON and other regulations such as rate control and section 1122. How can one tell which, if any, is responsible for a perceived change?
- - effectiveness may be highly dependent on the political environment and receptiveness to regulation.

More “Does CON Work?”

- According to Blumstein and Sloan, a “common analytical approach is to review certificate-of-need applications over a given period and monitor the percentage of applications disapproved and the amounts of capital expenditure avoided. “ But this does not account for projects that might have been initiated in the absence of CON but which weren’t filed because of anticipated rejection, what one might call the sentinel effect. Also, this evaluation technique can’t measure shifts in investment from regulated projects to unregulated projects.

More "Does CON Work?"

- Lewin and Associates found that:
- - because of costs involved and damage to the relationship with the regulatory agency, hospital administrators did not want to pursue projects that were likely to be rejected
- - CON resulted in increased planning and coordination among hospitals, including development of shared services and joint medical programs
- - CON accelerated timetables for facilities construction and introduction of special services
- - there was a belief that reviewers favored existing providers to the detriment of new entrants

More “Does CON Work?”

- The Macro research company concluded that:
- - hospital associations have been among the most active CON supporters
- - funding for the CON programs appeared to be inadequate
- - criteria to determine need are weak and poorly developed

More "Does CON Work?"

- Studies by Salkever and Rice, and by Hellinger revealed that:
- CON reduced bed expansion but increased expansion in plant assets per bed, the resulting impact being nil

More “Does CON Work?”

- - (Hellinger) concluded CON did not significantly reduce hospital investment – caution, however, that he did his research at a time when hospitals were believed to be accelerating investment to get it in under the wire before CON laws took effect in their states

More “Does CON Work?”

- Research by Sloan and Steinwald, and by Policy Analysis-Urban Systems Research and Engineering found few meaningful differences between CON and non-CON states.

- UNC project pegged at $143 million but omitted interest costs of $15 million. The project was $26.6 over budget and 95% built.
- West Virginia: regulators concerned because 98% of the applications between 1996 and 2000 approved.Two hospitals, 6 miles apart, wanted major projects ($265.2 million, 318 bed replacement hospital and a $75 million, 199 bed replacement hospital). Thirty five miles away, another hospital wanted $74.5 million, 51 bed expansion of it's 380 bed hospital. State considered denying both (in the 6 mile case) unless they collaborated on one proposal.

- According to Ralph Gladfelter, senior vice president for the Florida Hospital Association, there is “an unmistakable connection that exists between a program with high volumes and better outcomes.”
- Larry Horwitz, president of the Economic Alliance for Michigan, argues that “quality is enhanced when fewer physicians and institutions perform such difficult procedures as heart-bypass surgeries.”

- Also in Florida, hospital lobbyists opposed a bill in 2000 to end CON because they claimed it would threaten patient safety and the “economic vitality of hospitals that treat a high number of poor and uninsured patients. “ The Florida Hospital Association (200 members) said CON was needed to prevent over-expansion that erodes care quality.

- Gladfelter cited a study by the University of Iowa indicating that mortality rates are 21 percent lower in states with certificate of need programs compared with states that do not have them.

- A study in the Journal of the American Medical Association “identified 11 medical procedures and conditions in which volume was critical. At hospitals doing fewer than 30 abdominal aorta repairs, for example, patients were 64% more likely to die than at busier facilities.” Susan L. Meyers reported “While there have been no significant studies of how abolishing the health planning regulation affects health care costs, research shows that having too many specialty units in a market can affect patient safety.”

- In North Carolina, Blue Cross Blue Shield sought a lowering of the jurisdictional threshold from $2 million to $750,000 because manufacturers were cutting deals with hospitals to get in under the wire. That reform legislation also extended jurisdiction to doctors who set up free-standing laboratories and radiology centers because they have “lower overhead costs …often skim off a neighboring hospital’s profitable programs…”

- Duke University's Duncan Yaggy notes a less visible but perhaps more valuable benefit to CON, improved planning that happens at the facility level. Yaggy claims "[i]t's an important exercise because it really compels you to be sure that what you are doing is sensible, that it passes the red face test." It can also provide hospital executives "with a convenient excuse for not expanding," he said

More about Structural Problems

- Loopholes such as avoiding CON by leasing instead of purchasing .
- - Lack of competing applications
- - Political pressures, ex parte communications
- - Difficulty defining need
- - Difficulty evaluating new technologies
- - Ruling bodies lacking incentives to turn down applications:
- - Costs are spread across the system
- -

- - The “physician office” exemption that was intended to exempt the traditional, freestanding, independent doctor’s office from CON regulation but also allows large hospital-owned physician practices to escape review.
- - Providers have an incentive to push up their plans and be the first one to apply (except where applications are batched.
- - Sanctions are often lacking, ill-defined, inadequate, or counterproductive

- CON only addresses one part of the hospital cost pie. It does not limit non-capital expenses, the number of units of service provided, prices charged, staffing ratios, salaries, supplies and non-capital equipment, equipment below the thresholds, or utilization – the number of admissions, length of stay, procedures done, etc.

- Currently, Maine, Kansas, Maryland, and Minnesota are engaged in collecting data from a broader source, namely insurance claims data. Vermont's legislature has called for the state to implement a multi-payer claims based database. Through such data collection, almost all of a state's health care utilization could be analyzed, including hospital visits, doctors' visits, pharmacy expenditures, and even some alternative care expenditures.

- Evidence does not exist indicating deregulation is effective at slowing health care cost increases. From 1981 to 1991, a period of a significant push toward deregulation, there was a $448 billion rise in health care costs (from $290 billion to $738 billion), rising twice as fast as the consumer price index.

- Business coalitions pushed for re-regulation as a way to hold down costs for their members. Forces such as the Atlantic Health Care Alliance, composed of Coca-Cola, Delta Air Lines and BellSouth, argued for re-regulation.[ii] Georgia and Virginia responded to the pressures by expanding CON jurisdiction. In Georgia, the equipment threshold now applies to doctors' offices and free-standing clinics as well.

- Some hospitals and corporations think CON is a “critical brake against a costly proliferation of medical construction that would be unleashed on health care consumers” without it.

- Between Ohio's repeal of CON in 1995 and 2002
- ¨ 133 new ambulatory surgery facilities
- ¨ 26 new hospitals
- ¨ 38% increase in open heart surgery
- ¨ 82 new MRI or CT scanners
- ¨ 567 new psychiatric beds
- ¨ 8 new transplant services
- ¨ 14 new lithotripters
- ¨ 20 new obstetrical services
- ¨ 41% increase in rehabilitation beds
- ¨ 337 new med/surg beds
- ¨ 13 new radiation therapy services
- ¨ 1100 new heliodialysis stations

- In Michigan, auto makers and the United Auto Workers union have lobbied to block a CON repeal effort. Daimler Chrysler testified in March 2002 that its health care spending totaled $3,519 per employee or family member in Wisconsin and $2,741 in Indiana, two non-CON states, and $1,839 in Michigan and $1,331 in New York, two CON states. (Wisconsin is 91% higher than Michigan, 164% higher than New York, Indiana is 49% higher than Michigan and 106% higher than New York).
- Ford Motor Company released a study in February of 2002 showing it pays 12-39% more for certain patient services in Ohio and Indiana, which have repealed CON, than in Michigan and Kentucky, where CON still exists.

- Questionable research methodology, however, such as failing to account for cost differences in the states studied that are completely independent of CON's presence such as whether the factory was in a large city with a high cost health care system not attributable to CON or lack of CON.

- Former Colorado Governor Roy Romer regrets suspending the CON program in 1987: " I think it was a mistake. We've seen an explosion of costly and duplicative services since then."

- Between 1989, when Virginia abolished review of equipment such as M.R.I. machines, and 1992, the number of M.R.I. machines doubled to 58, and other equipment spending rose rapidly. David G. Brickley, a member of the Virginia House of Delegates proclaimed that “Our premise in 1989 was that health care was based on supply and demand. If there were more M.R.I. and C.A.T. scanners available, the price would go down. What happened was just the opposite. More machines are available, they’re not being fully used and costs are higher than ever.”
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- In Wisconsin, Governor Tommy Thompson reinstated CON in 1992 after repealing it in 1987

- managed care largely failed at the cost control effort because (1) it seriously under-priced its products in the 1990s to grab market share and counter the Clinton health care reform plan, and (2) was outmaneuvered by health care providers, mostly hospitals, that increased monopoly power through mergers and succeeded in characterizing the insurance companies as greedy, uncaring, faceless corporations.
- insurance market reforms such as coverage mandates, extensive appeal rights and less restrictive provider networks, cost managed care plans what marginally improved abilities they had to contain costs.

Heart Hospitals

- Perhaps the dominate modern CON battleground is in the field of heart surgery. The familiar issues: care quality, cherry picking of profitable lines of service, weakening of existing facilities, increasing overall system costs through duplication, excess investment and the behavior of covering stranded costs by hiking prices on other services.

Heart Hospitals

- Dr. Henry Meilman, chief of the cardiac catheterization lab at Union Memorial Hospial says that: “In Califorina, with a proliferation of heart surgical programs, the chance of dying is twice what it is in Maryland….Any heart program should be doing 800 cases, maybe even 1000 per year. …If you look at California, an average program is doing 90 cases…The medical literature is clear that a higher volume of cases produces better outcome

Case: Illinois Heart Hospital

- In 1999 CON regulation became a very controversial topic in Illinois as a coalition of entities led by Edward Hospital (in Naperville, 30 miles west of Chicago) submitted a CON application to construct a for-profit five-story "specialty" cardiac care hospital to be called, simply, Heart Hospital.
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- The opposition consisted of a group of seven charitable, not-for-profit hospitals from three Chicago area counties, calling itself "The Alliance for Governmental Action." All were allowed by the rules to participate as intervenors. They presented four complaints:
- 1. The proposal violated CON rules;
- 2. There was potential misuse of charitable assets;
- 3. There were fraud, abuse and physician self-referral concerns; and
- 4. There were threats to health planning and the orderly delivery of health care.
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- Loyola University Medical Center, one of the Alliance hospitals, had former Illinois Republican Governor James Thompson lobby the State Planning Board and Edward Hospital hired former Illinois House Republican Leader Sam Vinson to assist its cause.
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- Legislative controversy followed the Heart Hospital case. In April of 2000, Governor George Ryan signed a bill which significantly amended the CON law, raising thresholds and limiting board members' terms.
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Finally

- There is consensus that there is a cost crisis in health care. There is no consensus on whether to address it through a regulatory approach, a competition approach, or some other method.
- The current structure of the health care system, the public good aspect of its purposes, and the need to assure quality make it impossible to have a completely unregulated system. If CON is to be used as a cost containment tool, however, its limitations must be acknowledged and it must be designed in such a way as to maximize its costs and benefits.
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